John E. Calfee, Ph.D.

American Enterprise Institute
1150 17th St., NW, Washington, D.C.
202-862-7175 -- fax 202-862-7177 -- email: calfeej@aei.org

Written Testimony before the

Department of Health and Human Services

Task Force on Drug Importation

Tuesday, April 27, 2004

I am honored to testify before the HHS Task Force on Drug Importation. In my testimony, I will briefly address only two of the questions listed in the HHS document, "Detailed Drug Importation Questions For Task Force Public Docket and Meetings." These are: **(VIII)** Assess the potential short- and long-term impacts on drug prices and prices for consumers associated with importing drugs from other countries; and **(IX)** Assess the impact on drug research and development, and the associated impact on consumers and patients, if importation were permitted.

VIII. Assess the potential short- and long-term impacts on drug prices and prices for consumers associated with importing drugs from other countries

The price impact of mass drug importation depends strongly on what rules are established by legislation (cf. Calfee 2003a for additional details). If the law simply removes existing constraints while maintaining reasonable assurances of safety (a topic not addressed here despite its seriousness), there is little reason to expect prices in the U.S. to decline significantly in the short run. That is because most importation would presumably come from Canada, whose supplies are less than 5 percent of those in the U.S. in dollar terms and perhaps 6 to 8 percent in physical terms. Satisfying demand from just a few states would require far more than existing Canadian supplies.

Pharmaceutical manufacturers have made it perfectly clear, however, that they will not increase shipments to Canada sufficiently to cover demand for cross-border trade to the U.S. This is to be expected, because unlimited cross-border trade at Canadian prices would eliminate a substantial portion of industry profits, possibly one-third or more. Clearly, shipments south to the United States would be insufficient to materially reduce American prices. Canada, on the other hand, would find it impossible to keep their relatively small stocks from leaving for the U.S. Canadian authorities would have little choice but to raise price ceilings in order to undermine wholesalers' incentives to ship goods to the U.S.. In fact, Canadian drug prices have already begun to increase in the limited situations in which increases are permitted (Palmer 2004).

The longer run is more complicated. If mass importation extends to other nations with advanced pharmaceutical regulatory systems, including current European Union members, Australia, and New Zealand, supplies from those sources might eventually move in sufficient quantities to satisfy U.S. demand. (That demand would presumably be primarily for drugs used for chronic conditions and would not include those for acute care or hospital use, but even that is not certain.) If that happens, the adjustment period could involve severe changes. Manufacturers would again refuse to undergo the massive augmentation of European supplies necessary to satisfy mass importation, and European nations would soon encounter severe shortages. Alleviating those shortages would be a challenging task because it would involve preventing the free flow of goods. But pharmaceuticals in the European Union are now freely shipped across numerous national borders. The E.U. nations would probably not undertake the onerous and highly intrusive measures necessary to keep their low-price pharmaceutical supplies from leaching out of the European Union for shipment to the United States. Their only recourse would be to increase their price ceilings in order to remove the incentives for wholesalers to engage in mass arbitrage. Essentially, European pharmaceutical prices would have become linked to American prices.

The result would be a rough price convergence at a level somewhere between current U.S. prices and average prices abroad. Thus American prices would decline.

How large these price movements would be is difficult to assess because we do not know what uncontrolled prices in Europe would be. Danzon and Furukawa (2003) have documented in detail that in 1999, the disparity between American and European prices did not much exceed the disparity in per capita GDP. Price differentials may have increased significantly since 1999, but their results seem to suggest that U.S. prices in the face of mass importation might eventually decline by perhaps 15 to 25 percent while average European prices would climb by roughly the same amount (with large differences across individual nations and specific drugs).

Whether these changes will ever occur is far from certain, however. Somewhere in the process, politics could easily overtake economic forces. As the sole advanced nation without pharmaceutical price controls, the U.S. would come under severe diplomatic pressure to adopt controls in order to relieve European nations from the fiscal pressures driven by American pharmaceutical prices. The prospect of price controls in the United States raises serious questions about research incentives, which are treated in the section on Question IX.

It seems unlikely that Congress will pass such a simple, straightforward importation bill, however. Importation advocates recognize the logic just outlined. Current legislative proposals therefore include provisions that would prohibit firms from restricting supplies to price-controlled nations or would severely penalize them for restricting supplies (by defining such practices as violations of antitrust law, for example). If these measures generate the price dynamics their supporters obviously seek, the results would be quite different from those outlined above.

We would expect prices of the more expensive and heavily used drugs to descend toward the lowest nearby price (presumably one of the Canadian provinces). This process would require vigorous enforcement by American regulatory authorities, however, to ensure that manufacturers meet wholesaler demand to purchase at Canadian prices. It might also require rather intrusive regulation to determine which Canadian prices apply (because Canadian prices can be fairly dynamic). Shortages in Canada would almost

certainly occur as wholesalers rush to move existing supplies to the higher-priced U.S. market. Consequent disruptions to Canadian health care could be substantial.

Eventually, assuming the law works as its supporters apparently intend, American prices would be tied to certain Canadian or European prices. Those prices in turn would involve international linkages. Many Canadian price ceilings are set at the median prices of seven other nations. Those prices can and do change. In addition, currency fluctuations would quickly translate into price changes for the next wave of purchases by wholesalers. American health care organizations and American patients would find themselves in the strange position of awaiting the latest pricing decisions of certain Canadian provincial authorities, or perhaps authorities in certain small European nations such as Portugal, in order to learn what the price in the United States will be. A segment of the American health care system worth something on the order of $150 billion today would hinge upon the decisions of authorities representing a market of perhaps one or two billion dollars. Unpredictable perturbations in the form of reactions to national crises or institutional dynamics (the workings of German sickness funds, for example), could become greatly magnified in the American drug market. A Portuguese regulator could decide next year's price for a single drug whose American revenues exceed the entire Spanish or Portuguese market for *all* branded drugs. Another factor could be, again, intrusive regulation. European health systems would be tempted to increase their price ceilings while cutting complicated secret deals with drug manufacturers at what would effectively be lower prices. How a mass importation system would handle these arrangements is unclear.

Again, we could expect politics to overwhelm this unprecedented economic arrangement in which the United States has ceded a major determinant of its health care costs to diverse foreign regulators. Pressure to negotiate international price controls could prove difficult to resist.

IX. Assess the impact on drug research and development, and the associated impact on consumers and patients, if importation were permitted.

The impact on R&D of mass drug importation depends on what importation rules are enacted by Congress. I will focus on the second scenario described above, in which American prices tend to be forced down to price-controlled levels in one or more foreign nations such as Canada or certain Canadian provinces.

Economists are virtually united in their hostility to price controls in almost all markets that do not involve lawfully protected monopolies.[1] The usual objections are that controls generate shortages, suppress investment and innovation, cause distortions that can reduce efficiency, and create vested interests who seek to preserve price controls despite their costs. I will focus on a few points that are more or less peculiar to pharmaceutical markets.[2]

The absence of objective, reasonable, and predictable controls: No objective basis for "fair" or "reasonable" drug prices or profits exists (cf. Calfee 2001). Regulators of pharmaceutical prices cannot base prices on the value of drugs, because that would tend to mimic the very market prices that controls are supposed to correct. Controllers cannot set prices to encourage the "right" research because they lack the necessary information, such as the ultimate value of a particular drug or the likelihood of success of a specific line of research. Finally, basing prices on the actual development costs of individual drugs is neither practical nor appropriate. This is partly because research and administrative expenses are shared among numerous drugs and, sometimes, among several firms, some of whom may have failed to create a marketable drug at all. Regulators also have no objective and consistent way to assess the degree of financial risk

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[1] Patents, including patents for pharmaceuticals, are intended to create temporary monopolies, and are not subject to traditional economic criticisms of price controls.

[2] Among many treatments of pharmaceutical price controls is Danzon 2001, Ellison and Mullin 2001, Frank 2003, Newhouse 2004, and several articles by Danzon and her colleagues listed in the references section of this testimony.

that was overcome in the drug development process, including the research failures and bankruptcies that may have preceded the creation of a financially successful new drug.

The value of marketing: Even if it were feasible to construct controls that would preserve incentives for new drug development, serious problems would remain. One is that marketing is often necessary and valuable. Despite criticisms that marketing is wasteful, there are compelling reasons to believe that simply making a new drug available without marketing support is unlikely to allow the drug to achieve its full value to patients. The literature on the underuse of effective medical treatments, including pharmaceuticals, is large (and will not be cited here). Advertising and marketing can reduce undertreatment of patients and underuse of pharmaceuticals (Calfee 2003b and citations therein). It is hard to imagine how price controllers would handle the task of ensuring price levels sufficient to support marketing and distribution costs that ultimately work to the advantage of patients.

The value of post-drug-approval research: An even more serious difficulty lies in the fact that much of the most important research is conducted after a drug has been approved. Findings from post-approval research range from improved dosages (which may be smaller, so that the ability to raise prices may be necessary to provide adequate R&D incentives) to new uses (especially important in oncology, where there are literally scores of potential uses for a single drug) and ultimately, fundamental research on the very processes that drugs attack. An example of the latter are the striking findings from recent large clinical trials of the statin class of cholesterol-reducing drugs. These have transformed accepted views on the significance of serum cholesterol levels for both heart disease and strokes (Topol 2004). Ongoing revisions on the etiology of heart disease and heart attacks have received considerable publicity. Less noted is the fact that a recent article based on a statin trial was published in the "basic research" section of the American Heart Association's academic journal, *Circulation* (Horiuchi, et al. 2003).

These circumstances pose extraordinary difficulties for any price controls regime. It is doubtful that price regulators would authorize increases to cover the costs of new research, either prospectively when the research begins or after the research is completed,

knowing that, as with new drugs, the manufacturer will have no alternative but to continue selling the drug when the new research is done. Indeed, current price control policies appear to be focused purely on new drugs and often (as in the case of Canada) envision price freezes or cuts after approval. In national price control regimes, research-based price increases appear to be rare or nonexistent despite the value of much post-approval research. This is unfortunate. It is well known that many drugs prove to be far more valuable than was generally anticipated at the time of approval. Examples include the unexpected long-run success of SSRI antidepressants as well as the statins.

The absence of self-correcting forces: In most markets, price controls generate shortages and other obvious distortions, which in turn may lead to measures to relax or even bring an end to controls. An example of ameliorating measures are the annual adjustments to Medicare reimbursement levels made by CMS and Congress in the face of threats of exit by physician specialties and health care organizations. Such correctives can certainly lessen the harm from controls even if they cannot prevent harm altogether. Unfortunately, the pharmaceutical R&D market does not afford this essential check on price controls. Once controls are in place, no one will be able to identify the useful pharmaceutical R&D projects that have been curtailed or prevented. Because R&D takes so long, and involves such high financial risk, there is no substitute for the market incentives of handsome profits combined with severe financial penalties for failure, including bankruptcy. This is not an activity in which price controllers would be able to pick winners among hundreds or thousands of potential pharmaceutical research lines.

The difficulties in replacing privately funded R&D with publicly funded R&D: The National Institutes of Health has produced an extraordinary amount of basic research, laying the foundation for practical drug development. NIH rarely proceeds through the costly and financially risky sequence of clinical trials necessary for FDA approval. This has been recognized by federal government reports including reports from GAO and NIH itself. Nor is there is any reason to believe that the much smaller government and non-profit institutions of other nations will fill the gap. No matter how promising a research line is at the start, there is no substitute for the private market's

combination of payoffs for success and penalties for failure. An example of the lack of necessary market discipline is NIH's insistence on proceeding with funding of an international AIDS vaccine trial, at a cost of hundreds of millions of dollars, despite the fact that few if any prominent specialists believe the trial has even a modest chance of revealing a successful vaccine (Klausner, et al. 2004). The recent NIH initiative to bolster clinical research also illustrates the problem, as the new agenda is very much in the NIH tradition of funding very large numbers of small research efforts by independent scientists in the hopes that a few will generate striking results (Crowley, et al. 2004). This is quite different from a practical drug development agenda.

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